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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,423	11/27/1998	PHILIP S RUDLAND	WPT-0114-PUS	9634
22045	7590	11/05/2003	EXAMINER	
BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/101,423

Applicant(s)

RUDLAND ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears *n* th cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,11,15-19,23 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 11 is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,15-19,23 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11-27-98 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/03. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Amendment/Response filed 7-31-03 are acknowledged.
2. Amendments to claims 1, 15-17, 23 and 29 have been entered.
3. Claims 1, 2, 4-7, 11, 15-19, 23, and 29 pertaining to SEQ ID NO 4 are under consideration.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 17 and 29 recite a composition comprising a DNA adapted to target a regulatory DNA, which is not expressed as mRNA but that is capable of inducing metastasis as claimed in claim 7 and claim 11 respectively. It is noted that claim 7 and 11 are drawn to a regulatory DNA comprising the sequence of SEQ ID NO 4.

When the claims are analyzed in light of the specification, instant invention encompasses any composition comprising any DNA that is adapted to target the DNA of SEQ ID NO 4. However, the specification does not disclose any such compositions of DNA that could be adapted to target the claimed regulatory DNA. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, no targeting DNA compositions

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have been disclosed. The specification does not provide any disclosure as to what would have been the structure of a composition comprising DNA that is adapted to target the claimed regulatory DNA. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the specification does not describe any characteristics of any species of the claimed genus.

Accordingly, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that the applicant is in possession of the broad genus of the modulators or agents at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

6. Claims 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 17 and 29, as amended, recite the limitation "a composition comprising a DNA adapted to target a regulatory DNA....." however, the specification as filed does not disclosed any such composition. Applicants in their response did not indicate as to where in the specification the support for the term was present. Therefore, the term " a compositon comprising a DNA" is considered a new matter.

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C.112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. See MPEP 2163.06

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7. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 1-27-03.

### ***Response to Arguments***

Applicant's arguments filed 7-31-03 have been fully considered but they are not persuasive. Applicants that page 19 of the specification teaches the kit, however, these arguments are not persuasive because the cited "one sentence" is not sufficient to provide enabling disclosure for the claimed kit. It is noted that previous office action discusses specific scientific issues regarding the lack of enablement, however, applicants did not address any of the specific scientific issues.

8. Claims 17 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record of set forth in the previous office actions of 3-16-01, 12-4-01, and 1-27-03.

As noted in the previous office actions, the specification is not enabling for a compositions of DNA that is adapted to target the claimed regulatory sequence invention because the specification does not provide any guidance as to how the claimed composition would have been prepared, what parts of the regulatory DNA will be targeted, and what will the structure of the composition. It is noted that the only description provided by the specification is on page 19 (last 6 lines) and page 20, which indicates that oligonucleotides could be used for blocking the expression the function of a regulatory DNA in a cancer. The specification does not

provide as to what part of the DNA would have been targeted, what would be the structure of the antisense or ribozyme and how will the composition be used.

### ***Response to Arguments***

Applicant's arguments filed 7-28-03 have been fully considered but they are not persuasive. Applicants have argued that the after amendment the claimed invention is to a DNA composition not a medicament and therefore the enablement rejection is moot. It is noted that applicants have not provided any guidance how to make and use a DNA composition that targets the regulatory DNA of the instant invention. Additionally, the intended use of the composition is for blocking expression of a regulatory DNA in a cancer, therefore, the enablement of record still applicable to the amended claims. Applicants have not provided any arguments as to how the amended claims have any other use and wherein the specification any such use has been disclosed. Therefore, the enablement rejection is maintained for the reasons of record set forth in the previous office actions of 3-16-01, 12-4-01 and 1-27-03.

9. Claims 1-2, 4-6, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method wherein a fragment of human DNA of less than 1.5 kb in length, wherein said human DNA is obtained from malignant, metastatic cancer cells, wherein said fragment of human DNA is tagged at both ends with double-stranded synthetic oligonucleotides, and wherein said double stranded oligonucleotides provide restriction enzyme and unique PCR primer sites, is transfected into rat or mouse tumor cells that do not form metastatic tumor, the transformed tumor cells are injected into syngeneic rats or mice, rats or mice injected with transformed tumor cells are selected in which metastasizing tumors have been identified, and the regulatory DNA that induces metastasis are isolated and recovered from the metastasis tissue of the rats or mice, does not reasonably provide enablement for other claimed embodiments for reasons of record set forth in the previous office action of 3-16-01, 12-4-01 and 1-

27-03. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

### ***Response to Arguments***

Applicant's arguments filed 7-28-03 have been fully considered but they are not persuasive. It is noted that the scope rejection has been modified in view of applicants' arguments. However, Applicants' arguments and the arts cited are not persuasive to enable the full breadth of the claimed invention. Applicants argue that the three references provided describe a cell line that produces benign and non-metastasizing tumor when injected in a syngeneic animal and which when transfected with another DNA will produce metastasis". However, these arguments are not persuasive because these cell lines- taught by Vousden et al or Radler-Pohl et al are not any cell line, rather they are tumor cell lines and they are not introduced in any animal rather in a mouse or rat. Therefore, applicants' characterization of these reference as teaching "any cell line in any syngeneic animal" is incorrect. These references only teach that the method was known in mouse or rat and that a cell line that was transformed or isolated from tumor could be used.

**10.** The written description rejection of Claims 1-2, 4, 5, 18 and 19 has been withdrawn in view of applicants' arguments.

**11.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**12.** Claim 5, 6 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because it encompasses the invention of a cancelled claim therefore metes and bounds of the claimed invention are not clear. Claim 6 is dependent on claim 5.

Claim 19 is indefinite because it dependent on claim 3 which has been cancelled.

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. Claims 15 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasaki et al (US 5808024, 9-15-1998, filing date 6-7-1995) for reasons of record set forth in the previous office action of 12-4-01 and 1-27-03.

### ***Response to Arguments***


Applicant's arguments filed 10-15-02 have been fully considered but they are not persuasive. Applicants argue that after amendment the probe is less than 6000 bp in length, however, these arguments are not persuasive since nt 827-844 of Sasaki et al will still meets the limitation of at least 6000 bp.

18. As noted in the previous office action, claims 7 and 11 drawn to a regulatory DNA comprising the sequence of SEQ ID NO 4 are free of the prior art of record and are allowable.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

  
**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632